CROSSER® CTO Recanalization System

CTO OVERVIEW
CTO Prevalence

CTOs are a common occurrence in PAD – Reported in up to 40% of symptomatic patients¹

CTO Challenges

CTO procedure failures are primarily due to the inability to:

- Penetrate proximal cap
- Navigate side branches
- Re-enter distal true lumen

CTO Challenges

Failure to cross lesions, with possible procedure failure, may lead to important burdens such as lengthy procedures, increased radiation exposure, periprocedural complications, and repeat intervention\(^3,4\)


CTO Challenges

Clinical literature has shown CTO **crossing success rates** of 5% to 66% with **primary wire-catheter**

- This may result in **sub-intimal deflection** and subsequent dissection which may **impair and isolate the new lumen from collateral circulation**

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CTO Crossing – Definition of Success

• **Overall Crossing Success**
  – Overall crossing success measured by gaining wire access to the distal true lumen

• **Secondary Success**
  – Bail-out technique, often using a re-entry tool to access the distal true lumen from a subintimal channel
CTO Cap Morphology

PREFERRED STRATEGY: FOLLOW CONCAVITY ANTEGRADE

ANTEGRADE CONCAVE

RETROGRADE CONVEX

PREFERRED STRATEGY FOR INCONGRUOUS CAPS: ANTEGRADE-RETROGRADE

ANTEGRADE CONCAVE

RETROGRADE CONVEX

ANTEGRADE CONVEX

RETROGRADE CONCAVE

PREFERRED STRATEGY: FOLLOW CONCAVITY RETROGRADE

ANTEGRADE CONVEX

RETROGRADE CONCAVE

ANTEGRADE CONVEX

RETROGRADE CONCAVE

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Two Strategies for Recanalizing CTOs

- **Central Lumen Navigation**
  - Clinically preferred strategy
  - Maximizes therapeutic options
    - Adjunctive devices designed to operate in the arterial lumen

- **Subintimal Navigation**
  - Historical technique
  - Limits choices for adjunctive devices
  - Potential failure to re-enter distal true lumen
  - May result in impaired or lost collateral circulation

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True Lumen Crossing Matters

In the CENTRAL Study of SFA CTOs

- **90.7%** technical crossing success rate
- **Majority** of lesions were crossed intraluminally

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**Freedom from TLR at 6 Months**

18.4% higher 6 month freedom from TLR compared to subintimal crossing

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1 Intraluminal (true lumen) crossing is defined as ≥90% central lumen crossing; n=43
2 Majority subintimal crossing is defined as <50% central lumen crossing; n=13
3 Technical success is defined as the ability to cross the CTO in the central vessel lumen with the recanalization catheter and/or any conventional guidewire after the use of the catheter

Mechanism of Action

**Mechanical Impact**
- CROSSER® Catheter mechanically vibrates against the CTO
- Ultrasonic “Jackhammer”

**Cavitation**
- Micro-bubbles expand and implode breaking the internal fibrin structure of the plaque and eroding the solid surface of the CTO
Mechanical Vibration

• AC power from the CROSSER® Generator is transferred to transducer
  – Crystals within the transducer convert high frequency current into ultrasonic vibrational energy

• The core wire transmits mechanical vibration to the titanium tip of the catheter at:
  – 20,000 cycles/second
  – 20 micron amplitude (stroke depth) equivalent to 4 red blood cells
Plaque Ablation Selectivity

What is the result of this unique mechanism of action?
- Plaque ablation selectivity

The use of **ultrasonic vibration** by the CROSSER® System allows the device to automatically and **selectively ablate** inelastic material, such as plaque, while remaining **atraumatic to elastic tissue**.

Data on file. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results. A plaster stone was used in this demo.
Plaque Ablation Selectivity

- The CROSSER® Catheter tip selectively ablates inelastic material (i.e. calcium, plaque)
  - Plaque does not ‘flex’ / ‘give’ as the CROSSER® Catheter tip impacts the surface 20,000 times a second at a distance of 20 microns

- Atraumatic to elastic material (i.e. skin, vessel wall), the material will absorb the impact of the ultrasonic vibration
  - Similar concept to a medical saw to remove a cast

Data on file. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results. A plaster stone was used in this demo.
CROSSER® CTO Recanalization System

CTO PRODUCT PORTFOLIO
CTO Product Portfolio

CAPITAL EQUIPMENT

GENERATOR

INJECTOR

IV POLE
NOT INCLUDED

FOOT SWITCH
INCLUDED WITH CROSSER® GENERATOR

DISPOSABLE DEVICES

CROSSER® 14S
CTO Recanalization Catheter
5F

SIDEKICK®
Support Catheter
7F

CROSSER® S6
CTO Recanalization Catheter
5F

USHER®
Support Catheter
6F

STRAIGHT
ANGLED
STRAIGHT TAPERED
ANGLED TAPERED
Capital Equipment

**CROSSER® Generator**
- Converts AC power into high frequency current
- Piezoelectric crystals within the transducer convert high frequency current into vibrational energy

**FLOWMATE® Injector**
- Integrated saline infusion pump
- Precise activation and saline delivery

**Foot Switch**
- Control the procedure and pace of the CROSSER® System with a single foot switch
CROSSER® CTO Catheters

Indications for Use:
- The CROSSER® Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy

Contraindications:
- The device is contraindicated for use in carotid arteries
CROSSER® 14S Catheters

The Workhorse 5F Catheter (OTW & RX)

- "Support Taper" Transmission Wire
- 5F Sheath Compatible
- GeoAlign® Marking System
- Hydrophilic Coated
- Irrigation Outlets
- Radiopaque Marker Band
- 0.014” Guidewire Compatible
- 1.1mm Titanium Tip

CROSSER® Catheter Hub with Irrigation Port

OTW: 146cm Working Length with 152cm GW Lumen AND 106cm Working Length with 112cm GW Lumen

&

RX: 146cm Working Length with 20cm GW Lumen AND 106cm Working Length with 20cm GW Lumen
CROSSER® S6 Catheter

Focused Efficiency for Highly Calcified Lesions

- “Support Taper” Transmission Wire
- 0.6mm Stainless Steel Tip
- 5F Sheath Compatible
- Hydrophilic Coated
- 3 Irrigation Outlets
- Radiopaque Marker Band
- CROSSER® Catheter Hub with Irrigation Port
- GeoAlign® Marking System
- 154cm AND 106cm CROSSER® S6 Catheter Working Lengths
CROSSER® S6 Catheter

Focused Efficiency for Highly Calcified Lesions

- The small CROSSER® Catheter S6 tip focuses vibrational energy providing **twice the efficiency**\(^*\) of CROSSER® Catheter 14S

\(^*\) Bench testing results after 20 seconds CROSSER® Catheter activation in hard tile
SIDEKICK® Support Catheter

- Designed to **steer & support** CROSSER® 14S Catheter and **advance** through the vessel
  - For use with CROSSER® 14S Catheters
  - Stainless steel braided shaft for greater catheter push & torquability
  - 7F profile
  - 110cm & 70cm lengths
  - Hemostatic valve

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**STRAIGHT**  **STRAIGHT TAPERED**  **ANGLED**  **ANGLED TAPERED**
USHER® Support Catheter

- Designed to **steer & support** CROSSER® S6 Catheter and **advance** through the vessel
  - **For use with CROSSER® S6 Catheters**
  - Stainless steel braided shaft
  - Low profile tip transition
  - 6F profile
  - 130cm & 83cm lengths
  - Hemostatic valve
Support Catheter Hemostasis

- Hemostatic valve with every SIDEKICK® & USHER® Support Catheter
- Complete hemostasis to minimize blood loss during catheter/wire exchanges
- Decreases cost of case by eliminating need for a tuohy-borst
- Injection through side extension tubing port should only be done when CROSSER® Catheter is not in place
Providing exceptional CROSSER® Catheter Delivery, Support, Steerability and Visibility

- 0.014” Guidewire
- 1:1 Torque Transmission
- Lengths: 300 cm (3, 6, 9, 12g) and 195 cm (3, 6g)
- 3 cm Platinum Spring Coil on Tip for Visibility
- Hydrophilic Coating (Distal 42cm)
CTO procedures are associated with prolonged procedure time and increased radiation exposure²


*The GeoAlign® Marking System was evaluated in an animal study (repeat PTA in swine artery) to show a reduction in fluoroscopy time. The study was performed by 3 physicians who tested the LUTONIX® 035 DCB (no drug) and the ULTRAVERSE® 035 PTA Catheter, both with the GeoAlign® Marking System, to POBA with no GeoAlign® markings (n=112, test n=96 (with an average placement time of 66 seconds), control n=16 (with an average placement of 90 seconds)). Animal data on file. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.
GeoAlign® – Crossing

#1 Priority - Cross the CTO first
– Best practice
– Measure with GeoAlign® after
GeoAlign® – Measurement

Intravascular Length Measurement

Point A - Shaft Inserted 49cm

1cm 1cm

This is not intended to act as a substitute for, and does not replace, the relevant product information for use. Please consult instructions for use.
GeoAlign® – Measurement

Intravascular Length Measurement

1. Retract to distal cap
2. Retract to proximal cap
3. Subtract

Aid in PTA Length Selection

Point A - Shaft Inserted 49cm
Point B - Shaft Inserted 44cm

5cm

This is not intended to act as a substitute for, and does not replace, the relevant product information for use. Please consult instructions for use.
Increase procedure efficiency during repeat catheter placement

– Know where to go
– Incremental effect

*The GeoAlign® Marking System was evaluated in an animal study (repeat PTA in swine artery) to show a reduction in fluoroscopy time. The study was performed by 3 physicians who tested the LUTONIX® 035 DCB (no drug) and the ULTRAVERSE® 035 PTA Catheter, both with the GeoAlign® Marking System, to POBA with no GeoAlign® markings (n=112, test n=96 (with an average placement time of 66 seconds), control n=16 (with an average placement of 90 seconds)). Animal data on file. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.
**Rule of Thumb:** Look at the GeoAlign® markings of the device directly inserted into the guiding sheath (i.e. SIDEKICK®/USHER®)

- **Why?** All subsequent devices need to be compared against the same starting point

- **Exception:** Intravascular Measurement

Note: The GeoAlign® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy.
CROSSER® CTO Recanalization System

PROCEDURAL STEPS

For the CROSSER® 14S OTW Catheter
STEP 1
Prepare to Cross

- Position the guidewire to the lesion using an .014” guidewire
- Advance the SIDEKICK® Support Catheter over the guidewire and position towards the occlusion

Tips/Tricks
- Ensure guidewire does not engage the CTO cap and create subintimal tracks
STEP 2
Penetrate the Proximal Cap

- Retract guidewire 1 cm into the CROSSER® catheter
- Activate and sit on the proximal cap until the catheter is able to advance
- Advance CROSSER® slowly

Tips/Tricks
- Allow the CROSSER® Catheter to soften the CTO cap before advancing
- Use gentle forward pressure when advancing the CROSSER® Catheter
STEP 3
Traverse Mid-Occlusion

• Advance slowly and gently, allowing the CROSSER® catheter to pass through the occlusion

Tips/Tricks
• Mid-occlusion may be comprised of softer, organized thrombus and plaque
STEP 4
Support and Redirect

- Advance SIDEKICK® Support Catheter over the CROSSER® Catheter for distal support

Tips/Tricks
- Torque the support catheter to redirect the CROSSER® Catheter away from the vessel wall or collaterals as needed
STEP 5
Cross the Distal Cap

• Continue to advance the CROSSER® Catheter slowly

Tips/Tricks
• The distal cap is often calcified and angulated
STEP 6
Advance the Guidewire into the True Lumen

- The guidewire will advance easily if in the true lumen

Tips/Tricks
- Ability to exchange guidewires when using the CROSSER® OTW Catheters or support catheters
STEP 7
Remove CROSSER® Catheter and SIDEKICK® Support Catheter

- Keep guidewire in place
STEP 8
Deliver Subsequent Therapeutic Devices Over Guidewire

• If applicable, use the GeoAlign® Marking System to facilitate repeat catheter alignment with a subsequent GeoAlign® device
CROSSER® CTO Recanalization System

CLINICAL STUDY DATA
# CROSSER® Catheter Clinical Studies

**SINGLE ARM STUDIES OF THE CROSSER® CATHETER IN PAD PATIENTS.**
Inclusion of guidewire refractory patients is noted where data are available.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Artery</th>
<th>Lesion Characteristics</th>
<th>CTO Crossing or Procedure Success</th>
<th>Additional Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Igari 2015</td>
<td>16</td>
<td>42% SFA 32% Tibial 26% Peroneal</td>
<td>Mean length = 150 mm Grades 0-3 for calcification</td>
<td>Technical Success: 84%</td>
<td>0% device-related complications Activation time: 3.4 min</td>
</tr>
<tr>
<td>PATRIOT Laird 2014</td>
<td>85</td>
<td>61% SFA 20% Popliteal 17% Tibial/Peroneal 2% Other</td>
<td>Mean length = 118 mm 75% mod-severe calcification 100% Guidewire refractory</td>
<td>Technical Success: 84%</td>
<td>0% device-related clinical perforations CROSSER® Time = 14.3 min Activation Time = 2.1 min</td>
</tr>
<tr>
<td>CENTRAL 2013</td>
<td>100</td>
<td>100% SFA</td>
<td>Mean length = 132 mm Most mod-severe calcification 10% Guidewire refractory</td>
<td>Technical Success: 91%</td>
<td>90.0% freedom from limb loss and repeat revascularization</td>
</tr>
<tr>
<td>Staniloae 2011</td>
<td>56</td>
<td>14% Aortoiliac 49% FP 37% Tibial</td>
<td>Mean length = 131 mm 51.9% TASC D lesions</td>
<td>Technical Success: 77%</td>
<td>0% perforations CROSSER® Time = 17.6 min</td>
</tr>
<tr>
<td>Boguszewski 2010</td>
<td>17</td>
<td>94% SFA 6% Popliteal</td>
<td>Mean length = 170 mm</td>
<td>Technical Success: 100%</td>
<td>No evidence of distal embolization after lesion crossing</td>
</tr>
<tr>
<td>Gandini 2009</td>
<td>12</td>
<td>100% Infrainguinal</td>
<td>Median length = 260 mm 100% TASC D lesions 100% Guidewire refractory</td>
<td>Technical Success: 75%</td>
<td>0% perforation or dissection Time to cross lesion = 4.1 min</td>
</tr>
</tbody>
</table>
PATRIOT – Peripheral Study

85 Guidewire Refractory Peripheral CTO Patients

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Procedure Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% of lesions were resistant to conventional guidewire techniques</td>
<td>2 min 6 sec average CROSSER® Catheter activation</td>
</tr>
<tr>
<td>75% Moderate/severe calcium</td>
<td>36 min average fluoroscopy time</td>
</tr>
<tr>
<td>56% Complex CTO morphology</td>
<td>102 min average procedure time</td>
</tr>
</tbody>
</table>

Compelling Results

- 83.5% CROSSER® Catheter success rate in guidewire resistant CTOs
- Zero CROSSER® Catheter related clinical perforations
- 94.1% freedom from limb loss, clinical perforation & repeat revascularization through 30 days (80/85)
CENTRAL – Peripheral Study

100 SFA CTOs IVUS Evaluated for Intraluminal Crossing

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Procedure Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>74% Moderate/severe calcium</td>
<td>3 min average CROSSER® activation</td>
</tr>
<tr>
<td>132 mm Mean CTO length</td>
<td>35 min average fluoroscopy time</td>
</tr>
<tr>
<td>16.6 Month mean occlusion age</td>
<td>96 min average procedure time</td>
</tr>
</tbody>
</table>

Compelling Results

- **90.7%** technical crossing success rate\(^1\)
- **Majority** of lesions were crossed intraluminally\(^2\)
- **95.3%** 6 month freedom from TLR for lesions crossed intraluminally\(^2\)

\(^1\) Technical success is defined as the ability to cross the CTO in the central vessel lumen with the recanalization catheter and/or any conventional guidewire after the use of the catheter

\(^2\) Intraluminal (true lumen) crossing is defined as ≥90% central lumen crossing; n=43/85

Safety Information

Indications
- The CROSSER® Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The CROSSER® Catheter is only intended for use with the CROSSER® Generator. Refer to the CROSSER® Generator Manual of Operations for proper use.
- The SIDEKICK® and USHER® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

Contraindications
- The CROSSER® Catheter is contraindicated for use in carotid arteries.
- The SIDEKICK® and USHER® Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

As with most percutaneous interventions, potential adverse effects include: Bleeding which may require transfusion or surgical intervention, Hematoma, Perforation, Dissection, Guidewire entrapment and/or fracture, Hypertension / Hypotension, Infection or fever, Allergic reaction, Pseudoaneurysm or fistula Aneurysm, Acute reclosure, Thrombosis, Ischemic events, Distal embolization, Excessive contrast load resulting in renal insufficiency or failure, Excessive exposure to radiation, Stroke/CVA, Restenosis, Repeat catheterization / angioplasty, Peripheral artery bypass, Amputation, Death or other bleeding complications at access site.

Please consult package insert for more detailed safety information and instructions for use.

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